

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,513	04/08/2005	Rong Qi	CL001362-US	1176
Celera Genomi	7590 05/15/2007 CS	EXAMINER		
45 West Gude I	Drive C2-21	BUNNER, BRIDGET E		
Rockville, MD 20850			ART UNIT	PAPER NUMBER
			1647	
•		•	MAIL DATE	DELIVERY MODE
			05/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)			
Office Action Summary		10/506,513	QI ET AL.			
		Examiner	Art Unit			
		Bridget E. Bunner	1647			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) 又	Responsive to communication(s) filed on <u>08 Ap</u>	Responsive to communication(s) filed on 08 April 2005				
	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
/	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
,	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
	4)⊠ Claim(s) <u>1-23</u> is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.					
		willom consideration.				
· · · · · · · · · · · · · · · · · · ·	5)  Claim(s) is/are allowed. 6)  Claim(s) is/are rejected.					
·						
	_7) Claim(s) is/are objected to.  8) Claim(s) <u>1-23</u> are subject to restriction and/or election requirement.					
	·	section requirement.				
Applicati	on Papers					
9)[	The specification is objected to by the Examiner	r.				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
	Applicant may not request that any objection to the o	drawing(s) be held in abeyance. See	37 CFR 1.85(a).			
	Replacement drawing sheet(s) including the correction	on is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).			
11) 🔲	The oath or declaration is objected to by the Exa	aminer. Note the attached Office	Action or form PTO-152.			
Priority u	nder 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
2)  Notice 3)  Inform	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date	4) ☐ Interview Summary ( Paper No(s)/Mail Dai 5) ☐ Notice of Informal Pa 6) ☑ Other: <u>Appendix A</u> .	te			

Art Unit: 1647

## DETAILED ACTION

## Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2 and 20-21, drawn to an isolated peptide consisting of an amino acid sequence.

Group II, claim(s) 3, drawn to an isolated antibody that selectively binds to a peptide.

Group III, claim(s) 4-5, 8-11, and 22-23, drawn to an isolated nucleic acid molecule.

Group IV, claim(s) 6, drawn to a gene chip comprising a nucleic acid.

Group V, claim(s) 7, drawn to a transgenic non-human animal comprising a nucleic acid molecule.

Group VI, claim(s) 12, drawn to a method for detecting the presence of a peptide comprising contacting the sample with a detection agent that allows detection of the presence of the peptide in the sample.

Group VII, claim(s) 13, drawn to a method for detecting the presence of the nucleic acid molecule comprising contacting a sample with an oliognucleotide that hybridizes to said nucleic acid molecule.

Group VIII, claim(s) 14-16 and 19, drawn to a method for identifying a modulator of a peptide comprising contacting said peptide with an agent and determining is said agent has modulating the function, activity, or expression of the peptide.

Group IX, claim(s) 17, drawn to a pharmaceutical composition comprising an agent that binds to a peptide.

Group X, claim(s) 18, drawn to a method for treating a disease or condition mediated by a human transporter protein comprising administering an agent that binds a peptide.

2. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

This PCT rule defines special technical features as technical features that identify a contribution which each of the claimed inventions, considered as a whole, makes over prior art. Claims 1-2 and 20-21 are anticipated by prior art. Yue et al. (WO 2002/12340; 14 February 2002) teach an isolated polypeptide of SEQ ID NO: 28 that is 99.5% identical to the amino acid sequence of SEQ ID NO: 2 of the instant application (see sequence alignment attached to the instant Office Action as Appendix A). Therefore, claims 1-2 and 20-21 lack a special technical feature and cannot share one with the other claims.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37) CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found Art Unit: 1647

allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. <u>All</u> claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB Art Unit 1647 11 May 2007

> BRIDGET BUNNER PATENT EXAMINER

Dridget E. Burner

Appendix A

```
<!--StartFragment-->RESULT 2
 AAE21184
 ID
      AAE21184 standard; protein; 515 AA.
XX
 AC
      AAE21184;
XX
 DT
      01-JUL-2002 (first entry)
XX
DE
      Human TRICH-28 protein.
XX
KW
      Human; transporter and ion channel; TRICH-28; transport disorder; angina;
KW
      amyotrophic lateral sclerosis; cystic fibrosis; neuromuscular disorder;
KW
      cardiac disorder; polymyositis; diabetes; neurological disorder; cancer;
KW
      depression; schizophrenia; anaemia; Wilson's disease; Cushing's disease;
      cell proliferated disorder; infertility; arteriosclerosis; gene therapy;
KW
      Alzheimer's disease; Parkinson's disease; Huntington's disease; allergy;
KW
      myasthenia gravis; multiple sclerosis; metabolic disorder; hypertension;
      acquired immune deficiency syndrome; immunological disorder; scleroderma;
KW
KW
      endocrine disorder; autoimmune thyroiditis; rheumatoid arthritis; goitre;
KW
      cardiac myopathy; amnesia; toxic myopathy; Addison's disease; infection;
KW
      epilepsy; mental disorder; myocarditis; Crohn's disease; Grave's disease;
KW
     muscle disorder; stroke; dementia; anxiety; AIDS; asthma; cirrhosis.
XX
os
     Homo sapiens.
XX
     Key
                      Location/Qualifiers
FT
      Domain
                      77. .455
                      /note= "Monocarboxylate transporter domain"
FT
FT
     Domain
                      117. .135
FT
                      /note= "Transmembrane domain"
FT
     Domain
                      169. .191
                      /note= "Transmembrane domain"
FТ
FT
     Domain
                      190. .215
                      /note= "Transmembrane domain"
FT
FT
     Domain
                      229. .245
                      /note= "Transmembrane domain"
FT
FT
     Domain
                      376. .395
FT
                      /note= "Transmembrane domain"
XX
PN
     WO200212340-A2.
XX
PD
     14-FEB-2002.
ХX
PF
     01-AUG-2001; 2001WO-US024217.
XX
PR
     03-AUG-2000; 2000US-0223269P.
PR
     10-AUG-2000; 2000US-0224456P.
     18-AUG-2000; 2000U$-0226410P.
PR
     25-AUG-2000; 2000US-0228140P.
PR
     31-AUG-2000; 2000US-0230067P.
     08-SEP-2000; 2000US-0231434P.
XX
PA
     (INCY-) INCYTE GENOMICS INC.
XX
PΙ
     Yue H, Thornton M, Ramkumar J, Tang YT, Azimzai Y, Baughn MR;
     Yang J, Yao MG, Lal P, Walia NK, Gandhi AR, Hafalia AJA, Nguyen DB;
PΙ
     Patterson C, Elliott VS, Tribouley CM, Lu DAM, Xu Y, Reddy R; Hernandez R, Borowsky ML, Lo TP, Lu Y, Policky JL, Greene BD;
PΙ
PI
PI
     Sanjanwala MS, Raumann BE, Burford N, Ison CH, Lee EA, Ding L;
ΡI
     Das D, Kallick DA, Khan FA, Seilhamer JJ;
XX
DR
     WPI; 2002-206330/26.
DR
    N-PSDB; AAD33673.
XX
PT
     New human transporters and ion channels polypeptides and polynucleotides
PT
     for diagnosing, preventing or treating transport, neurological, muscle,
PT
     immunological and cell proliferative disorders.
xx
PS
    Claim 72; Page 193-194; 230pp; English.
ХX
CC
    The invention relates to human transporter and ion channel polypeptides
CC
    designated TRICH and nucleic acid molecules encoding such polypeptides.
    TRICH sequences are useful for diagnosis, treatment and prevention of
CC
     transport, muscle, neurological, immunological and cell proliferative
CC
    disorders. Transport disorders include akinesia, amyotrophic lateral
CC
     sclerosis, ataxia telangiectasia, cystic fibrosis, Becker's muscular
```

Appendix A (cont.)

```
CC
    dystrophy, diabetes mellitus, diabetes insipidus, myasthenia gravis,
    myocarditis, prostate cancer, cardiac disorders associated with transport
CC
     e.g. polymyositis, bradyarrythmia, dermatomyositis, angina, neurological
CC
     disorders associated with transport e.g. amnesia, bipolar disorder,
CC
     depression, Tourette's disorder, schizophrenia, other disorders
CC
     associated with transport e.g. neurofibromatosis, sickle cell anaemia,
CC
     Wilson's disease, cataracts, infertility, hyperglycaemia, hypoglycaemia,
     goitre, Cushing's disease, hypercholesterolaemia and cystinuria. Cell
    proliferated disorders include cancer, actinic keratosis, cirrhosis,
CC
CC
     arteriosclerosis, atherosclerosis, bursitis, hepatitis and psoriasis.
CC
     Neurological disorders include Alzheimer's, Pick's and Parkinson's
CC
     disease, amyotrophic lateral sclerosis, epilepsy, stroke, Huntington's
CC
    disease, multiple sclerosis, dementia and other extrapyramidal disorder,
    motor neuron disorder, prion disease, metabolic disease of the nervous
CC
    system and other developmental disorders of the central nervous system,
CC
    neuromuscular disorders, metabolic, endocrine and toxic myopathies,
    periodic paralysis, mental disorders including mood, anxiety; and
CC
CC
    immunological disorders include acquired immune deficiency syndrome
CC
     (AIDS), adult respiratory distress syndrome, Addison's disease,
CC
    allergies, asthma, atherosclerosis, osteoporosis, autoimmune haemolytic
CC
    anaemia, autoimmune thyroiditis, Crohn's disease, atopic dermatitis,
    Grave's disease, glomerulonephritis, rheumatoid arthritis, scleroderma,
CC
CC
    systemic lupus erythematosus, systemic sclerosis, ulcerative colitis,
    haemodialysis, uveitis; viral, bacterial, fungal, parasitic, protozoal,
CC
CC
    helminthic infections and trauma; and muscle disorders include cardiac
CC
    myopathy, myocarditis, polymyositis, arrhythmias and hypertension. The
    TRICH polynucleotides are used in gene therapy. The present sequence is
CC
    human TRICH-28 protein
XX
    Sequence 515 AA;
  Query Match
                       99.5%; Score 2660.5; DB 5;
                                                 Length 515;
  Best Local Similarity
                       99.8%; Pred. No. 1.9e-253;
  Matches 515; Conservative
                             0; Mismatches
                                                Indels
Qy
          1 MVLSQEEPDSARGTSEAQPLGPAPTGAAPPPGPGPSDSPEAAVEKVEVELAGPATAEPHE 60
            }
Db
           1 MVLSQEEPDSARGTSEAQPLGPAPTGAAPPPGPGPSDSPEAAVEKVEVELAGPATAEPHE 60
Qy
         61 PPEPPEGGWGWLVMLAAMWCNGSVFGIQNACGVLFVSMLETFGSKDDDKMVFKTAAWVGS 120
            Db
          61 PPEPPEGGWGWLVMLAAMWCNGSVFGIQNACGVLFVSMLETFGSKDDDKMVFKT-AWVGS 119
         121 LSMGMIFFCCPIVSVFTDLFGCRKTAVVGAAVGFVGLMSSSFVSSIEPLYLTYGIIFACG 180
Qy
            120 LSMGMIFFCCPIVSVFTDLFGCRKTAVVGAAVGFVGLMSSSFVSSIEPLYLTYGIIFACG 179
Db
Qу
         181 CSFAYQPSLVILGHYFKKRLGLVNGIVTAGSSVFTILLPLLLRVLIDSVGLFYTLRVLCI 240
            Db
         180 CSFAYQPSLVILGHYFKKRLGLVNGIVTAGSSVFTILLPLLLRVLIDSVGLFYTLRVLCI 239
         241 FMFVLFLAGFTYRPLATSTKDKESGGSGSSLFSRKKFSPPKKIFNFAIFKVTAYAVWAVG 300
Qy
            240 FMFVLFLAGFTYRPLATSTKDKESGGSGSSLFSRKKFSPPKKIFNFAIFKVTAYAVWAVG 299
Db
         301 IPLALFGYFVPYVHLMKHVNERFQDEKNKEVVLMCIGVTSGVGRLLFGRIADYVPGVKKV 360
Q۷
            300 IPLALFGYFVPYVHLMKHVNERFQDEKNKEVVLMCIGVTSGVGRLLFGRIADYVPGVKKV 359
         361 YLQVLSFFFIGLMSMMIPLCSIFGALIAVCLIMGLFDGCFISIMAPIAFELVGAQDVSQA 420
Qу
            <del>}</del>
         360 YLQVLSFFFIGLMSMMIPLCSIFGALIAVCLIMGLFDGCFISIMAPIAFELVGAQDVSQA 419
Db
         421 IGFLLGFMSIPMTVGPPIAGLLRDKLGSYDVAFYLAGVPPLIGGAVLCFIPWIHSKKQRE 480
Qy
            420 IGFLLGFMSIPMTVGPPIAGLLRDKLGSYDVAFYLAGVPPLIGGAVLCFIPWIHSKKQRE 479
Db
Qу
         481 ISKTTGKEKMEKMLENQNSLLSSSSGMFKKESDSII 516
            480 ISKTTGKEKMEKMLENQNSLLSSSSGMFKKESDSII 515
Db
<!--EndFragment-->
```